K111376 (pg 1/2)

BIOMET TRAUMA

AUG - 3 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	May 12, 2011
Applicant/Sponsor:	EBI, LLC 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300 x2260 Fax: 973-257-0232
Trade name:	Construx External Fixation System
Common Name:	External fixation system
Classification Name (Product Code):	KTT/Single/multiple component metallic bone fixation appliances and accessories
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3030

The purpose of this submission is to clear for marketing components of the Construx External Fixation System.

Device Description

The Construx External Fixation System consists of a central body, and several other components that can be used to create an external fixation frame. These components include:

- Male Stem Assembly
- Aluminum Ankle Assembly
- Carbon Ankle Assembly
- Carbon Straight Clamp Assembly
- Aluminum Male Straight Clamp
- Aluminum Female Straight Clamp
- Aluminum T-clamp
- Aluminum Angular Hinge Clamp
- Aluminum Ring Adapter

These components can be used with the DFS Bone Screws, and other components of the DFS Standard Fixator, DFS Ring and Vision External Fixation Systems.

Indications for Use

The Construx External Fixation System is a unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation modality.

Summary of Technologies

The technological characteristics (material, design and sizing) of the Construx External Fixation System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Construx External Fixation System (K953406/K021695/K023324)
- DFS Aluminum Ankle Assembly (K953406)
- DFS Carbon Ankle Assembly (K031919)
- DFS Carbon Fixator Straight Clamp (K040935)
- DFS Left and Right Telescoping Arms (K953406)
- DFS Angular Hinge Clamp (K953406)
- DFS Ring to Fixator Connector (K953406)

All of the named predicate systems were subsequently cleared for use in children in K081244.

Performance Data

Mechanical testing was performed on the Construx External Fixation System. Static and fatigue testing was performed on the new Construx components assembled as external fixation constructs. The new components met the established acceptance criteria set by the predicate devices.

Substantial Equivalence

The Construx External Fixation System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and have similar design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EBI, LLC
% Margaret F. Crowe
100 Interpace Pkwy.
Parsippany, NJ 07054

AUG - 3 2011

Re: K111376
Trade/Device Name: Construx External Fixation Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: May 13, 2011
Received: May 16, 2011

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

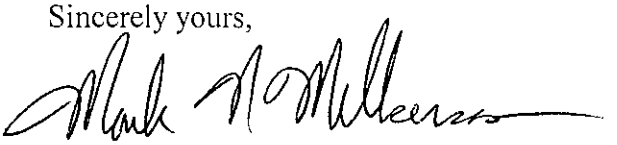
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111376 (pg 1/1)

Device Name: Construx External Fixation System

The Construx External Fixation System is a unilateral external fixation device intended for use in children and adults in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by the use of the external fixation modality.

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Temperature

Joan M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111376